

IAHCSMM

International Association of Healthcare Central Service Materiel Management

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TO: Docket No. 00D-0053
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources & Management Services
Food and Drug Administration
5630 Fishers Lane (HFA-305), Room 1061
Rockville, MD 20852

DATE: April 5, 2000

RE: Comments and Suggestions Regarding Draft FDA Guidance on
Reprocessing Single-Use Devices and Enforcement Strategy

The IAHCSMM welcomes the opportunity to comment on the above-mentioned documents.

Our initial overall reaction is appreciation of the time, thought, and effort that has obviously been spent by the Agency in starting to resolve the complicated problem of reuse of single-use devices. We are in sync with the direction in which the Agency is headed: protecting the patient by assuring the best level of practice possible is maintained in the reprocessing of single-use devices.

Because our position has always been that we do not recommend hospitals reprocessing single-use devices in-house, and because we favor regulation, we consider the timetables offered for the start of regulation to be reasonable. We agree that the agency's regulatory activities should be implemented in accordance with the risk involved; that approach is definitely in the best interest of the patient. We understand the rationale of phasing in the regulation and are in agreement with the 6-month, 12-month and 18-month plan.

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We do have some concern about completely eliminating "opened-but-unused" SUDs from the guidance document. While we agree that the risk of infection in such a situation is extremely low, the risk of inadequate performance could easily exist. An "opened-but-unused" SUD could "contain materials, coatings, or components that may be damaged or altered by reprocessing and/or resterilization/disinfection in such a way that the performance of the device may be adversely affected." We suggest that reprocessing and/or resterilization/disinfection of "opened-but-unused" high or moderate risk SUDs should require written recommendations from the manufacturer.

The Risk Categorization Scheme is ingenious and appears to have worked successfully in categorizing the list of frequently reprocessed SUD's. After working through the process of categorization according to the scheme, we felt that classifying into three categories, High, Moderate, and Low, was appropriate. This is particularly true with regard to the risk of infection. There is good correlation with the familiar Spaulding classification system of critical, semi-critical, and non-critical.

We did find what appeared to be discrepancies in the list of frequently reprocessed SUDs; this may be because we are not familiar with FDA procedures for classification. For instance, under Cardiovascular there is a needle, Regulation #870.1390, Procode DRC, that is in a High Risk Category; and a trocar, with the same Regulation number and Procode in the Moderate Risk Category. Several of our members noted that orthopedic flexible reamers/drills should be in the Moderate Risk Category because of difficulty in cleaning. We assume this list will be changed and updated as additional information is available, and we will forward any other comments we receive from our membership regarding the list.

The IAHCMM is an active member of the AAMI Sterilization Standards Committee, participating in the various working groups that write consensus standards for all aspects of medical device reprocessing. We favor the use of these performance standards wherever applicable.

The road ahead will be a challenge to all involved. Our offer to help in any way we can still stands. From our viewpoint, we are acutely aware of the responsibility to educate our membership in understanding and complying with the FDA enforcement and strategy on reprocessing single-use devices. Surely, it will be the patient who will profit the most from our efforts!

Lyndle Dorrell
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Lyndle Dorrell
IAHCSMM President

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